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(71) Applicant: ORDEV B.V.
Zandstraat 11
NL-4891 PP Rijsbergen(NL)

(72) Inventor: Hoffman, Erik Leonard
Mozartlaan 12
NL-4702 HL Roosendaal(NL)

(74) Representative: Smulders, Theodorus A.H.J., Ir. et al
Vereenigde Octrooibureaux Nieuwe Parklaan 107
NL-2587 BP 's-Gravenhage(NL)

(54) Self-adjusting prosthesis attachment.

(57) A tripartite set for securing a prosthesis to a bone, namely,
a proximal part (4) connected to the prosthesis and adapted to be received in a complementarily processed part of a marrow cavity;
a distal part or tip (8) to be fixed in said marrow cavity in an advanced position; and
a tie member (6) connecting said two parts, one end of said tie member extending at said tip (8) and forming a wedge bolt or like member which expands upon the exercise of tensile force therewith, and said tie member (6) being an at least axially resilient element with flat spring characteristics at least in the body temperature range.

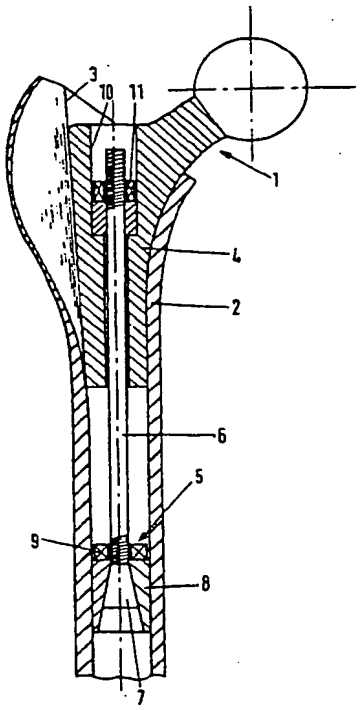

FIG.1

EP 0 403 028 A1

When the tip has thus been fixed, the proximal part of the attachment is secured in the fitting cavity in the bone by tensioning the tie member in the range of the superelasticity described. For this purpose use can be made of another property of shape memory metal, namely, a hysteresis in the temperature/stress curve. When, after heating, the metal is cooled, the shape recovery stress remains at the same level through a range of 10-15 °C. It is possible to select a shape memory metal with a higher transition temperature than the body temperature, e.g. 45 °C. At this temperature the range of superelasticity extends beyond the body temperature of 37 °C, e.g., 7% rather than 6% elongation. After an extension of 7%, the tie member is fixed in the proximal part. Even after the tie member has assumed the body temperature, the shape recovery stress remains in the higher range of superelasticity. During the introduction, a nitinol rod has room temperature of for example 20 °C, so that the force with which the rod is stretched is smaller than at the body temperature.

The set of proximal part, tie member and tip according to the invention lends itself excellently to modular construction, so that with a limited stock of parts optimally fitting assemblies can be made.

In an alternative embodiment of the invention the distal end of the tie member is not fixed to a tip but is threaded through a tube arranged in the medial femurcondyl and fixed at the end emerging from the lower end of said tube.

Some embodiments of the self-adjusting prosthesis attachment according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which

Fig. 1 shows diagrammatically a longitudinal part-sectional elevation of a prosthesis secured in a bone;

Fig. 2 is a part-sectional elevation similar to Fig. 1, showing a variant embodiment;

Fig. 3 is a diagrammatic illustration of a different embodiment of tip; and

Fig. 4 shows an alternative embodiment of the prosthesis.

In the embodiment of Fig. 4, a prosthesis 1 forming a part of a hip joint, is secured in a bone 2, the proximal part 3 of which has been prepared to adapt it in shape to the proximal part 4 of an attachment assembly further comprising a tip 5 and a tie member 6. The distal end of tie member 6 includes a wedge-shaped part 7, around which a number of segments 8 are arranged. Segments 8 have an outer wall formed as a part of a cylindrical or conical surface and an inner wall which is at least partly of tapered configuration, complementary to the wedge-shaped end part 7 of tie member 6.

For fixing the tip in the marrow cavity, the segments are pushed over the wedge-shaped end part 7 of the tie member by means of a nut 9 as a result of which the active diameter of the combination of segments is increased, by means of a specially designed tool.

Tensioning the proximal part 4 and thereby putting the tie member 6 under a stress can be effected by means of a nut 11, using the bottom of a recess 10 formed in the proximal part as a counter-bearing, or by means of a specifically designed tool.

The tie member is a rod with a diameter of about 4 mm and made of shape memory metal, in particular NiTi alloys, such as Ni 55 Ti 45, which have the property that they are capable of undergoing a martensitic structural change in the solid state, induced by stress, which is reversible and in the martensitic range has a shape recovery stress of constant value. This effect is called superelasticity.

In this concept, this property is used by stretching the shape memory metal in the austenitic phase, as a result of which it becomes stress-induced martensite, and this in the range with a flat distance/stress curve. When the elongation is consumed, the material automatically returns into the austenitic phase.

When the tip 5 has been fixed in bone 2, tie member 6 is stretched by tightening nut 11 at a temperature higher than the body temperature to within the superelastic or martensitic range associated with the temperature concerned. At a temperature of 45 °C, the rod 6 can be stretched by up to 7%. At the body temperature, the maximum elongation is about 6%. So long as the elongation has not been "consumed", the proximal part 4 is pulled in the direction of tip 5 with a constant force. The stress in rod 6 is consumed to prevent play both at the proximal part 4 and at tip 5.

In the variant embodiment of Fig. 2, the shape memory spring construction has been simplified, so as to make for a simpler surgical technique.

The shape memory spring is a straight wire 6a with a distal upset flange 6b with which a conical core 7a of a distal tip 5a can be axially displaced in a shell 8a of segments to change the active diameter thereof. For fixing spring 6a relative to the proximal part of prosthesis 4a, use is made of a hollow conical wedge 12.

To secure the prosthesis in a bone, the wedge assembly 7a, 8a of tip 5a is placed at a given depth in the intermedullary canal. The shape memory spring is tensioned whereby the upset flange 6b pulls core 7a into the segmented shell 8a, and thus tip 5a is secured. Subsequently, the shape memory spring, which has a sufficient excess of length, is tensioned and by means of the hollow conical wedge 12 clamped to the proximal part 4a

of the prosthesis. The projecting part of spring 6a is cut off.

This procedure is simpler than that which must be followed with the embodiment of Fig. 1. In fact, owing to the absence of threaded zones on the spring, any desired length of spring can be used as a starting product, and hence the tip can be positioned at any desired site. Also, screwing the spring to the proximal prosthesis part, using a torque spanner can be omitted.

As there is no friction between a pre-stress bolt 11 and the proximal part of the prosthesis, the tensioning of the spring is better reproducible. As the spring 6a is more flexible than the thicker spring 6, its flexibility is higher, and locking against loosening from vibration is no longer necessary.

Furthermore, the rod is thinner, simpler and hence less expensive. Other advantages of a smaller diameter and of more flexibility of the rod are that the number of prostheses which must be kept in stock can be reduced, because the flexibility of the spring permits using a symmetrical proximal part. Furthermore, owing to the smaller diameter with equal tensile force, a higher shape recovery stress can be achieved. With an equal hysteresis stress loss between tensioning and relax phase of the shape memory spring, the femur needs to be overloaded to a lesser extent during tensioning.

Fig. 3 diagrammatically shows a variant embodiment of the tip with a shape memory spring 6c of nitinol or other spring material, for instance maragin steel. Attached to the lower end of spring 6c are three downwardly diverging members or blades 13 of spring steel with hooks 14. To introduce tip 5c, use is made of a sleeve 15, which keeps blades 13 in folded-together condition. When tip 5c has been placed in position, sleeve 15 is pulled up. Blades 13 then spring outwards and the hooks become fixed in bone 2 during the contraction of spring 6c.

In the alternative embodiment of Fig. 4 the memory spring 6d is threaded through a tube 17 arranged in the medial femurcondyl 18. After tensioning either distally or proximally, the distal end of spring 6d is fixed to a plate 16 at the outside of 18. The proximal end of tube 17 is positioned by a centralizer 19.

Claims

1. A tripartite set for securing a prosthesis (1) to a bone (2), namely,
a proximal part (4) connected to the prosthesis and adapted to be received in a complementarily processed part (3) of a marrow cavity;
a distal part or tip (5) to be fixed in said marrow cavity in an advanced position; and
a tie member (6) connecting said two parts, one end of said tie member extending at said tip and forming a wedge bolt or like member which expands upon the exercise of tensile force therewith, and said tie member being an at least axially resilient element with flat spring characteristics at least in the body temperature range.

2. A prosthesis attachment as claimed in claim 1, characterized in that the tie element is a rod (6) of shape memory metal.

3. A prosthesis attachment as claimed in claim 2, characterized in that the rod of shape memory metal (6) has a diameter of about 2 mm and hence a high flexibility.

4. A prosthesis attachment as claimed in any of claims 1-3, characterized in that the distal tip (5) is provided with a plurality of circumferentially distributed segments (8), whose outer surfaces form parts of a cylindrical surface or conical surface, and whose inner surfaces taper towards one end, one end (7) of the tie member being substantially complementarily wedge-shaped and being disposed between the segments (8), there being provided means (9) for mechanically fixing said wedge-end (7) in axial direction relatively to said wedge segments (8) and the nitinol rod.

5. A prosthesis attachment as claimed in claim 4, characterized by a sleeve which may or may not form part of a tensioning tool with an end stop which is slid over said tie member and through the exercise of force from the proximal end, and through said end stop, forces the segments over the wedged end of said tie member, and fixes it to the nitinol rod.

6. A prosthesis attachment as claimed in claim 4, characterized by a nut (9) in operative association with a threaded portion of said tie member, said nut being arranged to be tightened with a spanner from the proximal end to fix said tip (5).

7. A prosthesis attachment as claimed in any of the preceding claims, characterized by a modular construction of the constituent parts.

8. A prosthesis attachment as claimed in any of claims 2-7, characterized in that the shape memory metal of the tie member is an NiTi alloy.

9. A prosthesis attachment as claimed in claim 1 or 2, characterized in that the rod of shape memory metal (6a) has a diameter of about 1.5 mm.

10. A prosthesis attachment as claimed in claim 9, characterized in that the distal tip (5a) is provided with a plurality of circumferentially distributed segments (8a), whose outer surfaces form parts of a cylindrical surface, and whose inner surfaces taper towards one end, there being further provided a core (7a) of substantially complementary wedge shape, said core being disposed between said segments (8a) and said memory spring

(6a) has an upset flange (6b) engaging with said core (7a).

11. A prosthesis attachment as claimed in claim 10, characterized by a hollow conical wedge (12) for the exercise of power on, and the fixation of, said spring (6a) on the proximal part (4a) of the prosthesis (1).

12. A prosthesis attachment as claimed in any of claims 1-9, characterized in that the distal tip is provided with three circumferentially distributed blades made of spring steel and diverting downwardly and outwardly from the end of said memory spring (7) with hooks extending outwardly and upwardly at the free lower ends of said blades.

13. A tripartite set for securing a prosthesis (1) to a bone (2), namely,

a proximal part (4) connected to the prosthesis and adapted to be received in a complementarily processed part (3) of a marrow cavity;

a distal part in the form of a plate member (16) to be fixed in an advanced position such as adjacent the medial femurcondyl; and

a tie member (6) connecting said two parts, one end of said tie member extending through a distally arranged threading tube inserted in said medial femurcondyl and fixed at the outer face thereof, said tie member being an at least axially resilient element with flat spring characteristics at least in the body temperature range.

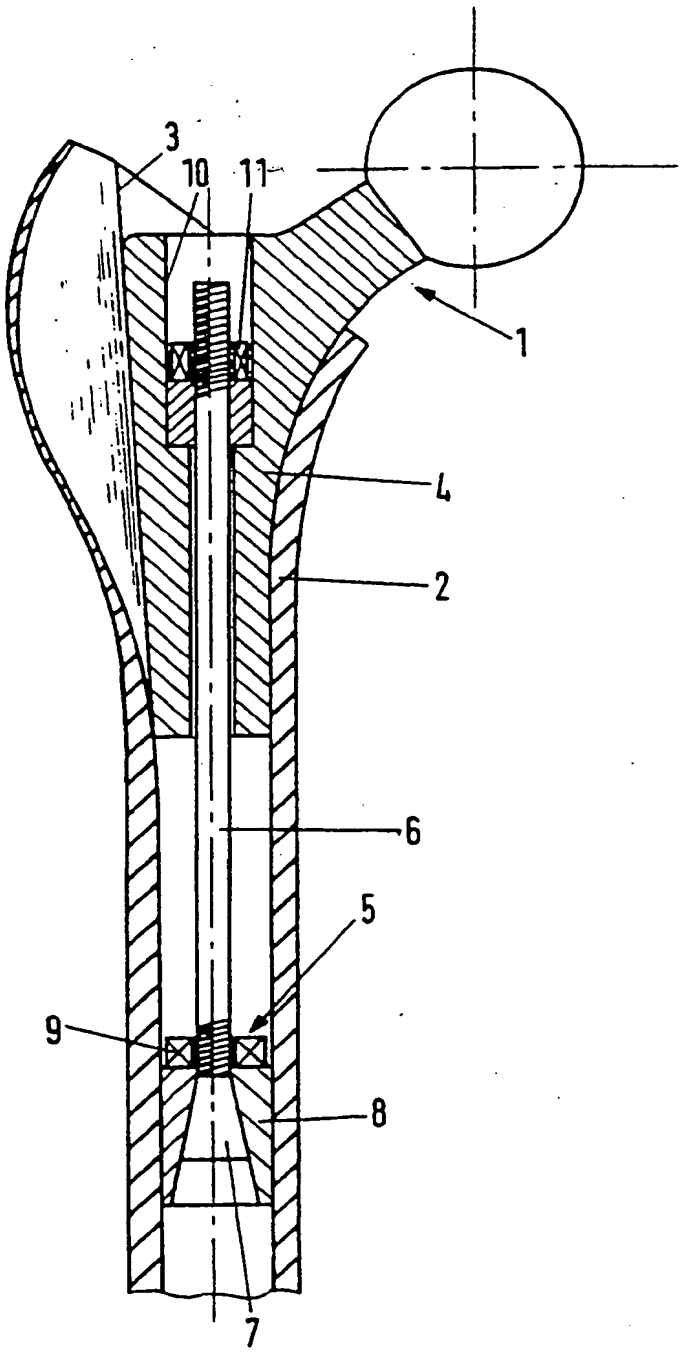

FIG.1

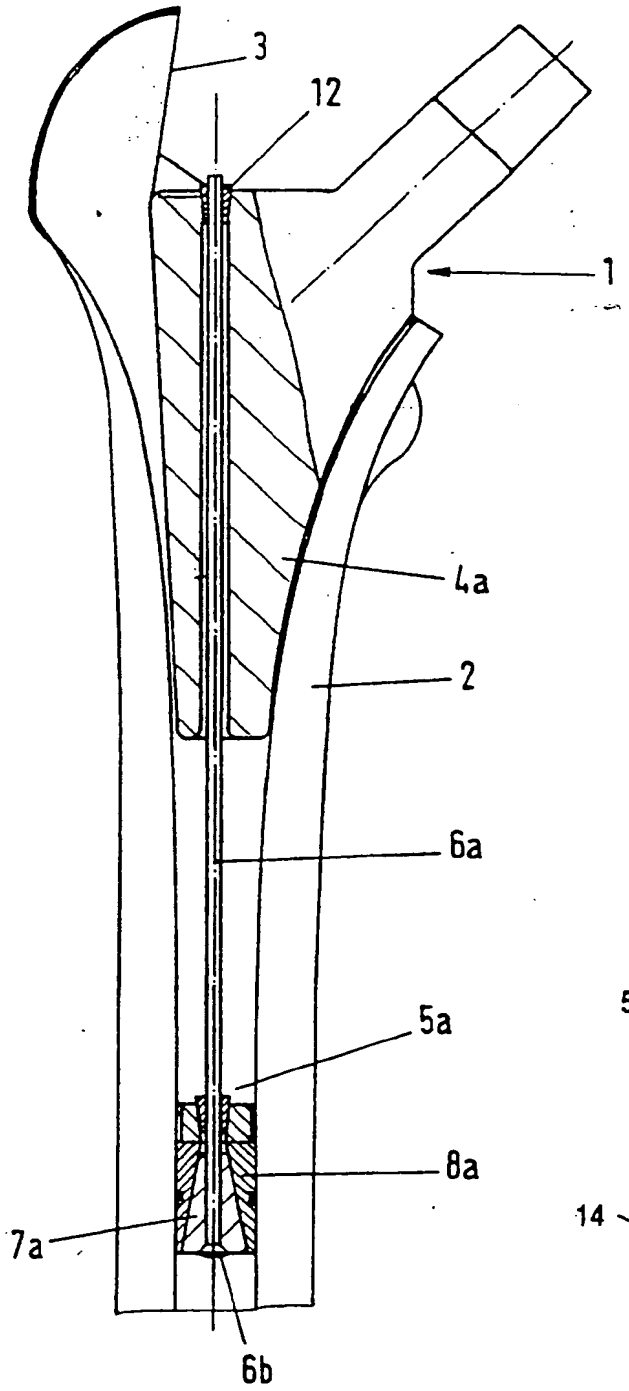

FIG. 2

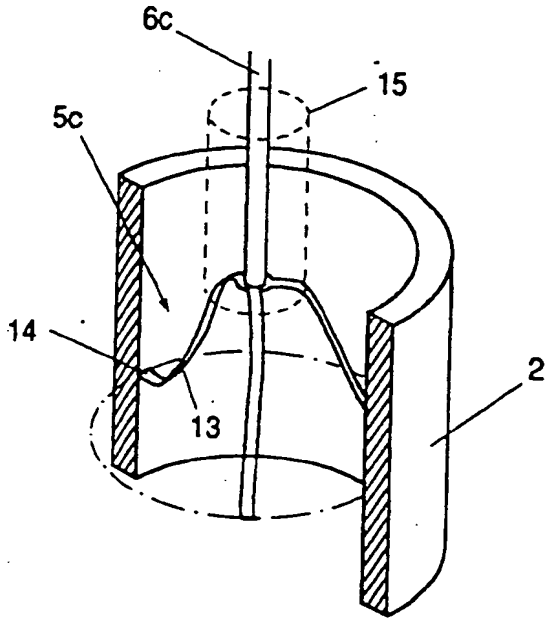

FIG. 3

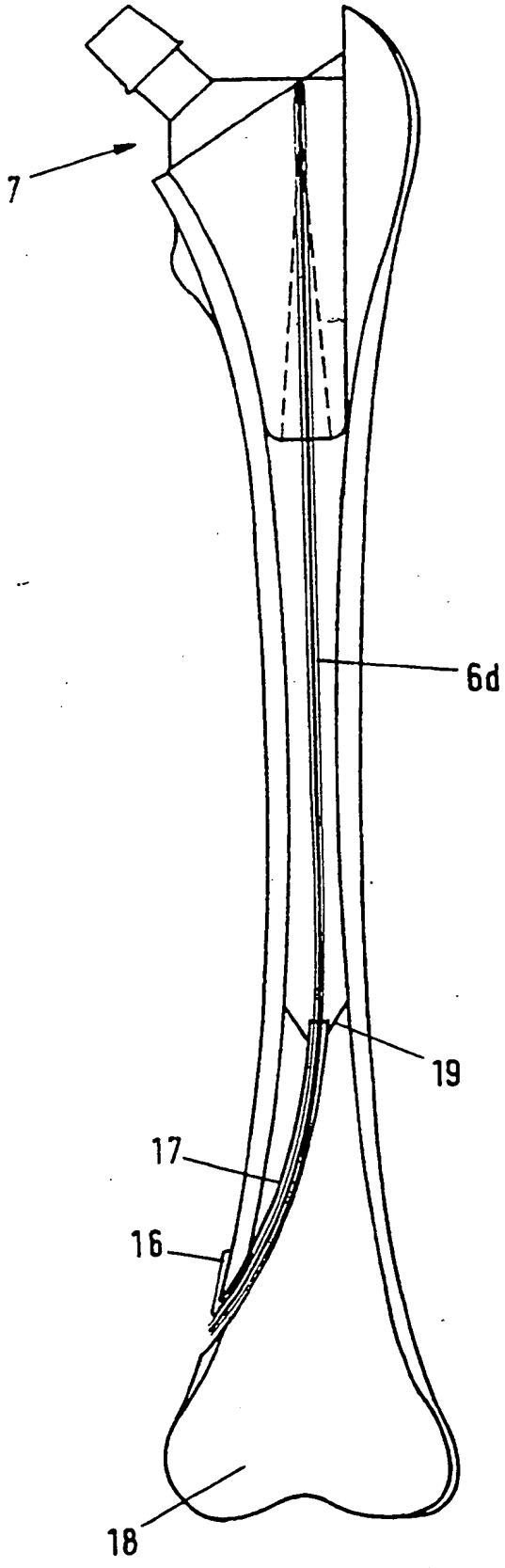

FIG.4

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EUROPEAN SEARCH REPORT

Application Number

EP 90 20 1556

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	EP-A-0 243 298 (MECRON) * Column 3, line 27 - column 7, line 28; figures *	1,4,5,7	A 61 F 2/36
A	WO-A-8 602 260 (BRUCE)		
A	GB-A-2 055 295 (ROALSTAD)		
A	US-A-4 011 602 (RYBICHI)		
D,A	EP-A-0 311 208 (ORDEV B.V.)		
P,A	EP-A-0 358 399 (KELMAN)		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F
A 61 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	24-09-1990	STEENBAKKER J.

CATEGORY OF CITED DOCUMENTS

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